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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/545,998

04/10/00

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EXAMINER

TUNG, M

ART UNIT

PAPER NUMBER

1644

*3*

DATE MAILED:

07/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

# Office Action Summary

Application No.  
09/545,998

Applicant(s)  
Gorman, et al.

Examiner  
Mary B. Tung

Art Unit  
1644



-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-22 are subject to restriction and/or election requirements.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

***DETAILED ACTION***

***Election/Restriction***

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
  - I. Claims 1-5 and 12 drawn to the 312C2 protein, a fusion protein and composition, classified in class 530, subclass 350; class 424, subclass 185.1; class 514, subclass 21.
  - II. Claims 6, 7 and 12 drawn to an antibody, classified in class 530, subclass 387.9.
  - III. Claim 8, drawn to a method of purifying 312C2 protein, classified in class 530, subclass 413.
  - IV. Claims 9-11, 12, 17, 19 and 20, drawn to a nucleic acid, vector, and a method of expressing 312C2 protein, classified in class 536, subclass 23.5, class 435, subclasses 69.1 and 320.1.
  - V. Claim 13, drawn to a method for detecting 312C2 protein, classified in class 435, subclass 4.
  - VI. Claims 14-16, drawn to a method of modulating a cell, classified in class 435, subclasses 69.1, 375 and 377.
  - VII. Claim 18, drawn to a tissue, cell or organism, classified in class 435, subclasses 325 or 347, or class 800, subclass 2.
  - VIII. Claims 21 and 22, drawn to a method of treating a mammal, classified in class 424, subclasses 139.1 or 185.1, or class 514, subclass 44.
2. Groups I, II, IV, V and VIII are unique products. They differ with respect to their physicochemical properties and are therefore patentably distinct.
3. Groups III, VI, VII and IX are unique methods. They differ with respect to ingredients and method steps. The method of purifying the 312C2 protein of Group III would not suggest the method for detecting 312C2 in a sample as recited in Group VI. Nor would the methods of Groups III and VI suggest the treatment of cells or mammals as recited in Groups VII or IX, respectively. Additionally, a method of treating a cell in Group

VII would involve different steps, reagents and materials than a treatment of a mammal in Group IX. They are therefore, patentably distinct each from the other.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and classifications, and because a non-patent literature and/or sequence search of any or these three distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is proper.
5. Should Applicants traverse on the ground that the members of the groups are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the members to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.
6. Irrespective of whichever group the applicant may elect, the applicant is further required under 35 U.S.C. 121:
7. If Groups V, VI, or VIII are elected, the applicant is further required to elect a **specific embodiment**: protein, nucleic acid or antibody.
8. If Group VII is elected, the applicant is also required to elect a **specific embodiment**: tissue, cell, organ or organism.
9. If Group VI is elected the applicant is further required to elect a **specific modulation of physiology**: apoptosis of T cell or activation of T cell.
10. If Group VIII is elected, the applicant is further required to elect a **specific abnormal immune response**: T cell deficiency, chronic inflammation or tissue rejection.
11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
12. Applicant is required, in response to this action, to elect a specific species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

13. Should Applicants traverse on the ground that the members of the species are not patentable distinct, Applicant should submit evidence or identify such evidence now of record showing the members to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

14. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

15. The following claim(s) are generic: claims 13-15, 18, 21-22.

16. The species are distinct each from the other for the following reasons:

17. The recited products, protein, antibody or nucleic acid have different biochemical characteristics, structure and functions.

18. The recited cell, tissue, organ or organism are different in their properties, morphological appearances and physiological function.

19. Apoptosis of T cells and activation of T cells are opposite cellular responses and would be measured using different reagents, steps and involve different cellular mechanisms.

20. T cell deficiency, chronic inflammation, and tissue rejection are different abnormal immune responses, with different etiologies, clinical presentations and treatment modalities.


21. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

22. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

***Conclusion***

23. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.
24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Tung whose telephone number is (703)308-9344. The examiner can normally be reached Tuesday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

July 2, 2001  
Mary B. Tung, Ph.D.  
Patent Examiner  
Group 1640

  
**MARY BETH TUNG, Ph.D.**  
**PATENT EXAMINER**